Washington State Department of Labor and Industries
Office of the Medical Director
Technology Assessment

# MedX Lumbar Extension Machine for the Treatment of Low Back Pain

November 7, 2003

## Introduction

Patients with low back pain may limit their lumbar movement because of pain. Due to pain, patients may perform tasks with pelvic movement instead of lumbar movement. (Nelson 1995) As a result, the gluteal and hamstring muscles grow stronger while lumbar muscles weaken. (Pollock 1989)

The MedX lumbar extension machine addresses low back pain by developing spinal muscle strength through a stabilization system that isolates specific muscle groups. (Nelson 1999) Stabilizing the pelvis isolates the lumbar extensor muscles by eliminating the contribution of the muscles that rotate the pelvis backward. (Graves 1994) The stabilized pelvis prohibits lateral, vertical, or rotational movement, thereby ensuring isolation of the back extensors. (Leggett 1999)

The MedX includes an upper thigh restraining belt and femur restraint pads that prevent vertical movement of the thighs or pelvis. Cranking the footrest forward exerts a force along the legs. This force pushes the pelvis back against a lumbar pad. In this manner, the lower extremities anchor the pelvis against the pelvic restraint to prevent pelvic rotation. (Graves 1992)

The MedX may also be used to measure voluntary isometric torque[1] of the lumbar extensor muscles at 7 positions through a 72º ROM. The 7 positions are 72, 60, 38, 36, 24, 12, and 0º of lumbar flexion. A load cell attached to the movement arm of the machine measures isometric torque. A video display terminal provides visual feedback to the subjects. (Graves 1994)

During training, subjects extend back against the upper back pad over 2 to 3 seconds. Then, they maintain the maximal tension contraction for 1 more second before relaxing. In general, subjects exercise with an amount of weight that allows 8 to 12 repetitions before volitional fatigue. When subjects complete more than 12 repetitions, weight load is increased by 5%.

The MedX Utilization Steering Committee has provided guidelines for the appropriate use of MedX. The guidelines indicate that only a clinician certified in the use of MedX equipment at the University of Florida or the University of California, San Diego should render services. (MedX 1995)

## FDA Status

In 1989, the MedX Corporation received 510(k) approval from the FDA for its MedX Rehabilitation Machine. The device was classified under the name "system, isokinetic testing and evaluation." (FDA 1989) In 1990, the MedX Cervical Extension Test & Rehab Machine received approval under the same classification name. (FDA 1990) In 1991, the FDA granted approval for the MedX Machine under the same classification name. (FDA 1991)

[1] Studies have examined the test-retest reliability of MedX for measuring lumbar isometric strength. In the study conducted by Robinson, reliability coefficients ranged from .66 to .93 for male subjects and from .59 to .96 for female patients. Reliability was greater in the flexed positions. (Robinson 1992) A study by Shirley showed that MedX measurements are highly correlated to measurements form a liquid inclinometer. (Shirley 1993)

Several studies have been conducted with healthy, asymptomatic study populations to determined MedX's effectiveness in strengthening lumbar extensor muscles. Study designs range from case series to randomized controlled trial. (Appendix A)

## I. Case Series with Healthy Subjects

a. Udermann's study compared EMG activity of the lumbar, gluteus, and hamstring muscles during trunk extension exercises with and without pelvic restraint. Researchers hypothesized that the restrained condition would result in greater activation of the lumbar extensors than the unrestrained condition. (Udermann 1999)

After electrodes were placed bilaterally over the hamstring, gluteal, and lumbar muscles, subjects performed an isometric contraction at 72º of lumbar flexion. Next, the subjects completed 2 sets of dynamic lumbar extension exercises with a resistance equal to 80% of their body weight. One set used the restraint system to restrict pelvic rotation. The other set occurred without pelvic stabilization.

Study Population: The study included 12 male volunteers who were asymptomatic of low back pain. Their average age was 25 years.

Results: Comparison of Restraint System on EMG Activity by Muscle Group

| | Muscle Groups | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | L1 | | L5 | | Gluteal | | Hamstring | |
| | Left | Right | Left | Right | Left | Right | Left | Right |
| Unrestrained | 24.7 | 25.5 | 35.0 | 34.4 | 11.6 | 12.7 | 31.1 | 40.5 |
| Restrained | 28.8 | 29.7 | 36.9 | 39.4 | 15.0 | 15.8 | 37.2 | 40.1 |

EMG activation in the restrained condition was slightly greater than in the unrestrained condition for all muscle groups. The difference represented about 10% (L5 and hamstring) to 27% (gluteal) more activity in the restrained condition. However, the differences were not statistically significant.

Conclusion: Pelvic restraint does not significantly increase the neural drive to the lumbar musculature during lumbar extension exercise in the seated position.

## II. Comparison Studies with Healthy Subjects

a. Graves studied whether limited ROM lumbar extension training would produce limited ROM strength benefit in asymptomatic subjects. Subjects trained once per week for 12 weeks. (Graves 1992)

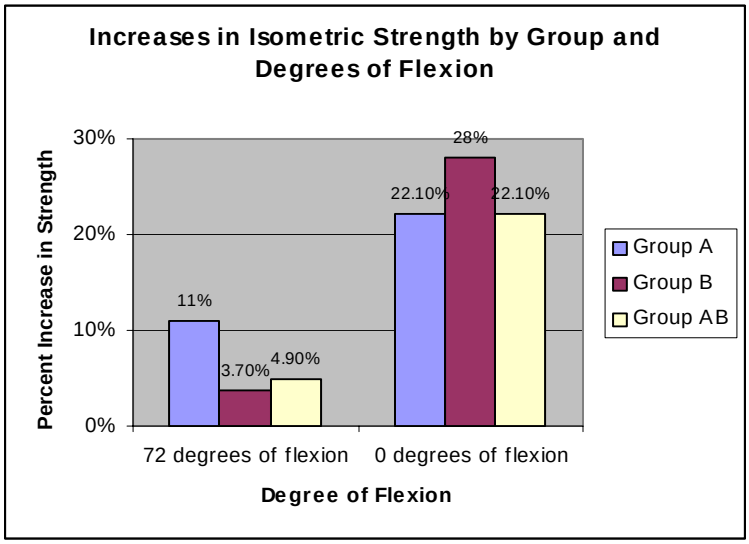
Patients were divided into groups:
1. Control group (n=10) did not train.
2. Group A (n=18) trained in a ROM from 72 to 36º of lumbar flexion.
3. Group B (n=14) trained in a ROM from 36 to 0º of lumbar flexion
4. Group AB (n=16) trained through a 72º ROM.

Intraclass correlation coefficients determined the reliability of the repeated measurements of isometric torque.

Study Population: The study included 58 volunteers.

Results: Reliability (intraclass correlation) coefficients between the two tests were high ($R \geq .92$) at each angle of measurement except 0º ($R = .81$).

All training groups showed a significant improvement in isometric strength at each angle when compared with the controls. A and B experienced the greatest gains in strength in their training ranges, but they did not differ significantly from AB at any angle.




The repeated measurements of isometric lumbar extension strength made at multiple joint angles were highly reliable, even when the testing is conducted in different orders.

Conclusion: The strength gained from limited ROM training was similar to that of full ROM training. Therefore, people who are able to train through 36º of lumbar motion may still obtain a full ROM training benefit.

b. Pollock used the MedX lumbar extension machine to determine the effect of variable resistance training on lumbar extension strength. Subjects performed one set of full ROM exercise with a weight load that allowed 6 to 15 repetitions. Researchers assigned subjects to either a training group (n=15) or to a control group that did not train (n=10). Subjects trained 1 day per week for 10 weeks. (Pollock 1989)

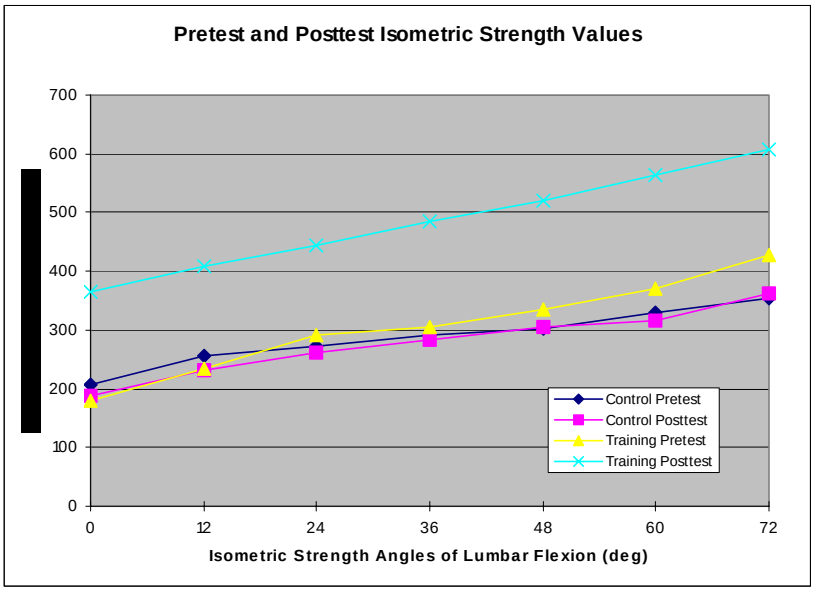
Study Population: The study included 25 healthy volunteers who had been participating in a regular exercise program for at least 1 year.

Subject Demographic

| Variable | Control | Training |
|---|---|---|
| Age | 33.7 years | 29.1 years |

| | | |
|---|---|---|
| Height | 176.2 cm | 179.5 cm |
| Weight | 76.5 kg | 83.1 kg |

Results: Lumbar extension strength at all angles improved significantly for the training group, but did not change in the control group. The training group significantly improved in the amount of variable resistance weight lifted to fatigue.




Conclusion: Exercising one day per week with isolated lumbar extension exercise can substantially increase the strength of the lumbar extensor muscles after 10 weeks of training.

## III. RCT with Healthy Subjects

a. Graves examined lumbar extension strength after resistance exercise with and without pelvic stabilization in an asymptomatic population. (Graves 1994)

Subjects were randomly assigned to one of the following groups:
1. P-STAB trained on the MedX lumbar extension machine
2. NO-STAB (n=41) trained on a Nautilus or Cybex Eagle lower back machine that restrains the legs from vertical movement, but does not stabilize the pelvis.
3. Control (n=15) did not train.

ROM for the P-STAB group was limited to 72º of lumbar extension. Compound trunk extension for the NO-STAB group was through a ROM of approximately 90º.

Study Population: The study included 77 volunteers who had no history of chronic low back pain and no contraindications to resistance exercise training.

Patient Demographic

| Group | N | Age (years) | Height (cm) | Weight |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| P-STAB | 21 | 34.6 | 174.4 | 76.7 |
| NO-STAB | 41 | 31.7 | 172.8 | 73.1 |
| Control | 15 | 29.1 | 176.3 | 74.3 |

Results: Both training groups significantly increased the amount of weight used to complete one set of 8 to 12 repetitions. Increase in training loads were 29% for the NO-STAB group and 39% for the P-STAB group. However, differences between groups were not statistically significant.

Isometric torque production of the lumbar extension muscles increased an average of 23.5% for the P-STAB group compared to the control group. Increases ranged from 9.0% at 48º of lumbar flexion to 120% at 0º of lumbar flexion. Training without pelvic stabilization did not improve torque production capacity of the isolated lumbar extensors compared to the control group.

Conclusion: The researchers found that resistive exercise training with and without pelvic stabilization improves dynamic trunk extension strength. However, pelvic stabilization is required to isolate and strengthen the lumbar extensor muscles.

b. Graves studied the effects of repeated isometric testing on lumbar extension strength. Training was conducted for 12 weeks. (Graves 1990)

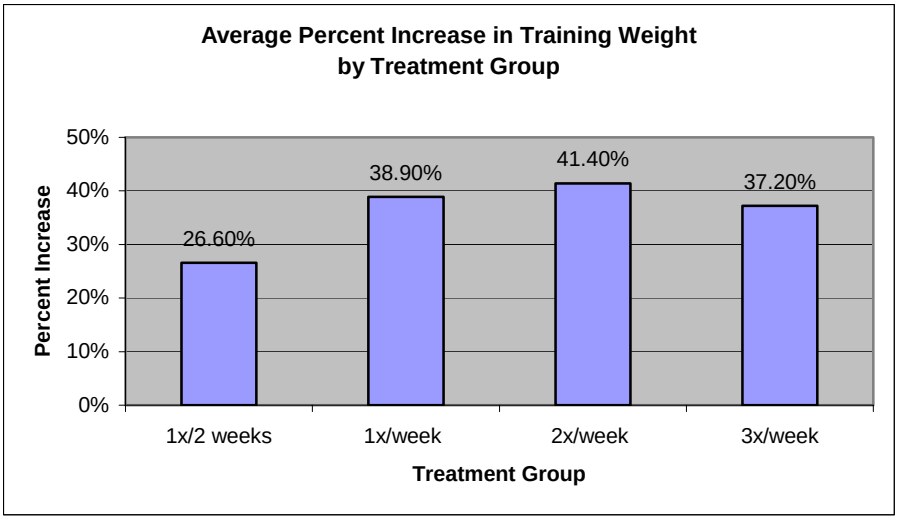
The researchers rank ordered subjects by peak isometric strength and randomly stratified them to one of 5 training groups or a control group that did not train. Four groups trained dynamically:

1. Once every two weeks (1x/2 weeks)
2. Once per week (1x/week)
3. Twice per week (2x/week)
4. Three times per week (3x/week)

The fifth treatment group trained isometrically once per week (IM 1x/week)

Study Population: Of the initial 170 volunteers, 114 subjects completed the study. 41 subjects elected not to complete the 12 weeks of training. Five experienced minor orthopaedic discomfort and discontinued training. Researchers excluded from analysis 10 subjects who completed training, but did not give a satisfactory effort during the isometric testing.

Results: When compared with the control groups, the groups that trained 1x/2 weeks, 1x/week, 2x/week, and 3x/week improved significantly in their ability to generate isometric torque throughout the full ROM. However, these training groups were not statistical different from each other in the magnitude of their training responses. Improvement in isometric torque ranged from 11.5% to 18.6% at the fully flexed position (72º) and from 53.7% to 129.7% at the most extended position (0º).




The researchers did not detect statistical differences in change in training weight when the 1x/week, 2x/week, and 3x/week were compared.

Training frequencies of 1x/2 weeks and 3x/week were all equally effective at improving isometric strength of the lumbar extensors. Training 1x/2 weeks was less effective for improving dynamic strength.

The researchers indicate that one subject could not tolerate a training frequency of 3x/ week.

Conclusion: Variable resistance exercise training at frequencies of 1x/2 weeks, 1x/ week, 2x/week, and 3x/week are all effective at improving isometric and dynamic strength of lumbar extensors during the first 12 weeks of training. Therefore, the researchers recommend training 1x/week.

Several studies have been conducted with to determine MedX's effectiveness in treating low back pain by strengthening lumbar extensor muscles. Study designs range from case series studies to randomized controlled trials. (Appendix A)

## I. Case Series with Low Back Pain Patients

a. Physical therapists saw patients twice per week for an hour. Subjects performed aerobic exercise and intensive strength training that did not stop because of pain exacerbation. Lumbar extensor, cervical extensor, torso rotator, cervical rotator muscle groups were isolated. Weight load was increased to allow 20 repetitions during each workout. (Nelson 1999)

   Objective measurements included static strength at predetermined points throughout the ROM, dynamic endurance, and ROM in both the sagittal and rotational (transverse) planes. Dynamic endurance was defined by the amount of weight and the number of repetitions a patient could perform until reaching volitional muscular fatigue. Pain was rated with a 10-point VAS. The final measure of treatment efficacy was whether the patient underwent surgery in the follow-up period.

   Response to treatment was rated as:
   - Excellent – resolution or near resolution of spine and extremity pain, normal or near normal strength values
   - Good – substantial but not complete pain relief, substantial strength gains
   - Fair – minimal pain relief, minimal or no strength gains
   - Poor

   Treatment ended when the subject:
   1. was pain free or nearly pain free and objective functional levels were at or near normal.
   2. was no longer making objective gains.
   3. refused to cooperate, a response to treatment that was recorded as a poor outcome.

   After discharge, patients were instructed in a home maintenance program.

   Mean follow-up occurred an average of 16.2 months after the patient's last clinic visit.

   Study Population: Of the 651 cervical and lumbar patients who were referred to the program, 62 patients met the study's inclusion criteria. Two patients elected not to enter the program, and 46 completed treatment. The average patient age was 42 years, and the average duration of symptoms was 28 months. 90% of patients had previously failed an exercise program.

   Results: Of the original 46 surgical candidates completing the program, 38 (82.6%) were located for follow-up.

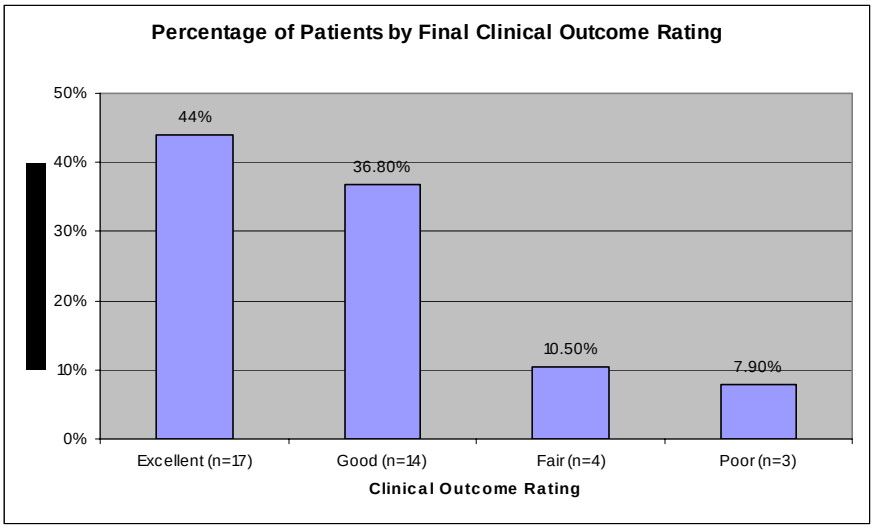
   Objective dynamic endurance increased significantly. The statistically significant strength gains ranged from 62% to 134%.

Extensor Muscle Strength Gains

| | Starting weight load | Ending weight load | Weight load increase |
|---|---|---|---|
| Lumbar extensor muscles | | | |
| Men | 79.4 | 136.0 | 72% |
| Women | 49.4 | 88.0 | 87% |
| Cervical rotator muscles | | | |
| Men | 207.0 | 334.0 | 61% |
| Women | 110.6 | 182.2 | 65% |

Rotator Muscle Strength Gains

| | Starting weight load | Ending weight load | Weight load increase |
|---|---|---|---|
| Lumbar extensor muscles | | | |
| Men | 44.9 | 72.0 | 60% |
| Women | 22.3 | 43.5 | 95% |
| Cervical rotator muscles | | | |
| Men | 54.7 | 102.3 | 87% |
| Women | 30.1 | 70.5 | 134% |




Three of the 38 patients needed surgery in the follow-up period.

b. Leggett's study documents two centers' results of treating patients with clinical low back pain (CLBP) with a progressive, restorative exercise program. The program included several types of exercise: high-intensity back strengthening, general strengthening for major muscle groups, cardiovascular, and ranging exercises. Physical therapists, clinical exercise physiologists, and athletic trainers provided treatments. (Leggett 1999)

When a patient could achieve 15 repetitions through the patient's full range at 50% of maximum isometric torque, the resistance was increased by 2% to 5%.

Strength change evaluated specific lumbar muscle improvement. The SF-36 determined perceived health change, treatment pain, and other subjective information.

Study Population:

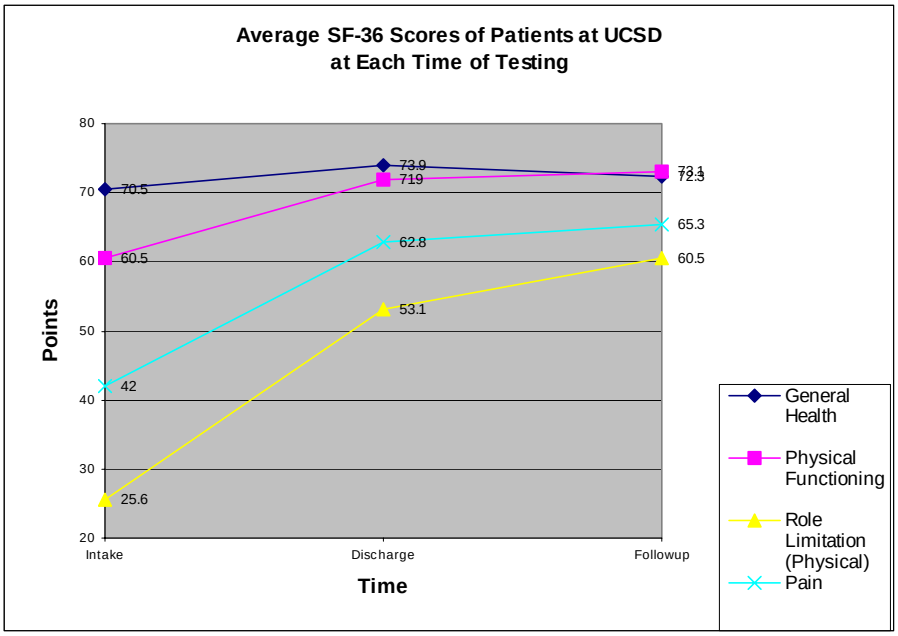
Number of Patients Entering and Completing Program by Site

| | UCSD | Minneapolis |
|---|---|---|
| Entered program | 1025 patients | 645 patients |
| Completed program | 714 patients | 360 patients |
| Completed 1-year follow-up | 310 patients | 102 patients |

The analysis only included patients who completed 16 visits.

The average duration of symptoms was 17 months. 11% of the UCSD participants and 14% of the Minneapolis participants reported one previous spine surgery. 5% of participants at both sites reported more than 2 previous surgeries.

Results: Flexion and extension back strength increased significantly from intake to discharge at both UCSD and Minneapolis.




Comparison of Mean MedX Strength between UCSD and Minnesota at Time of Testing

| | Intake | | Discharge | |
|---|---|---|---|---|
| Variable | UCSD | Minneapolis | UCSD | Minneapolis |
| Extension | 80.3 | 82.1 | 120.3 | 146.5 |
| Flexion | 142.3 | 150.3 | 184.0 | 220.2 |
| ROM | 54.5 | 52.5 | 61.5 | 58.7 |

75% of Minneapolis and 82% of UCSD reported that they were better.

Conclusion: Standardized protocols using specific strength and measurement equipment can achieve similar benefits at different sites.

## II. Studies on Low Back Pain Patients with Comparison Groups

a. Holmes conducted a study on lumbar extension strength among healthy, geriatric female patients compared to symptomatic, geriatric female patients seeking medical attention for low back pain. (Holmes 1996)

Study Population: The study included 38 female subjects with an average age of 68.3 years. Physicians referred 18 chronic pain patients (INJ) to the active rehabilitation program. Subjects' diagnoses ranged from degenerative disk disease to post-surgical fusion. The comparison group consisted of 20 healthy subjects recruited from a community adult fitness program. The comparison group had been in an aerobic or combined aerobic and strength training program for at least 6 months.

None of the subjects received workers' compensation or disability.

All subjects were tested at common test angles within their pain-free ROM. If patients felt pain or discomfort, they were instructed to discontinue extension. Patient ability to perform 20 controlled repetitions determined exercise workload. Patients who could tolerate higher intensity exercise sessions maintained a one-time per week regimen. Patients who could not tolerate higher intensity exercise maintained a two-time per week regimen.

The researchers also used a 10-point VAS to evaluate pain in the INJ group.

Results: Comparison between Pretreatment and Posttreatment Outcomes

| | Before treatment (INJpre) | After treatment (INJpost) |
|---|---|---|
| Subjective ratings of pain | 5.3 | 2.1 |
| ROM | 59.2 | 68.1 |
| Number of repetitions | 11.0 | 16.1 |
| Dynamic isotonic exercise resistance weight | 21.5 | 36.9 |

The comparison group was significantly stronger than the INJpre group at all testing angles. After rehabilitation, the INJpre and post scores differed significantly. However, differences between the INJpost and the comparison group were not significant.

Conclusion: Specific lumbar extension exercises that increase lumbar extension strength are associated with decreased subjective levels of pain and increased ROM. They have been demonstrated as useful for the conservative treatment of low back pain in older women.

b. Nelson studies whether intensive, specific exercise would effectively treat chronic low back pain. (Nelson 1995)

Patients were treated an average of twice per week for one-hour and required an average of 18 visits to complete the program. Treatment ended when the patient was:
1. Pain free or nearly pain free. Functional levels were at or near normal.
2. No longer making objective gains in spinal function.

3. Refusing to cooperate.

Physical therapists supervised the sessions, which included aerobic exercise and strength training of other muscles. Subjects continued the exercise for as many repetitions as possible while maintaining full ROM. All patients were also assigned a home program of progressive resistive exercises of the trunk muscles.

The study measured progress with isometric tests, changes in sagittal and rotational ROM, and sagittal and rotational dynamic work capacity. Patients rated their back pain, leg pain, and functional ability as greatly improved, improved, slightly improved, unchanged, or worse.

Study Population: Out of an initial 895 eligible patients, 627 patients completed the program. The 107 patients who elected not to enroll in the program acted as a comparison group. 161 patients began the program, but dropped out before completion.

Of the 627 patients who completed the program, 139 had been unemployed due to spinal pain. Their unemployment averaged 73 days at the time of presentation.

Patient Demographic

| Category | Percent of Patients |
|---|---|
| Workers' compensation recipient | 47% |
| Undergone previous surgery | 14% |
| Failed exercise program | 89% |
| Employment Status | |
| Employed without restrictions | 36% |
| Employed with restrictions | 24% |
| Employed secondary to their back problem | 22% |
| Unemployed | 10% |
| Student, Retired, or Disabled | |

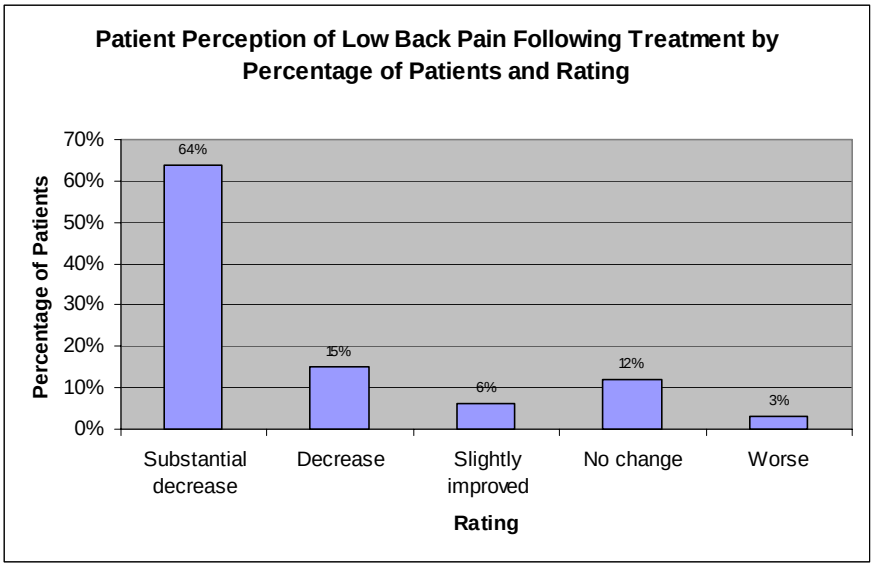
Numbers of Patient at Follow-up

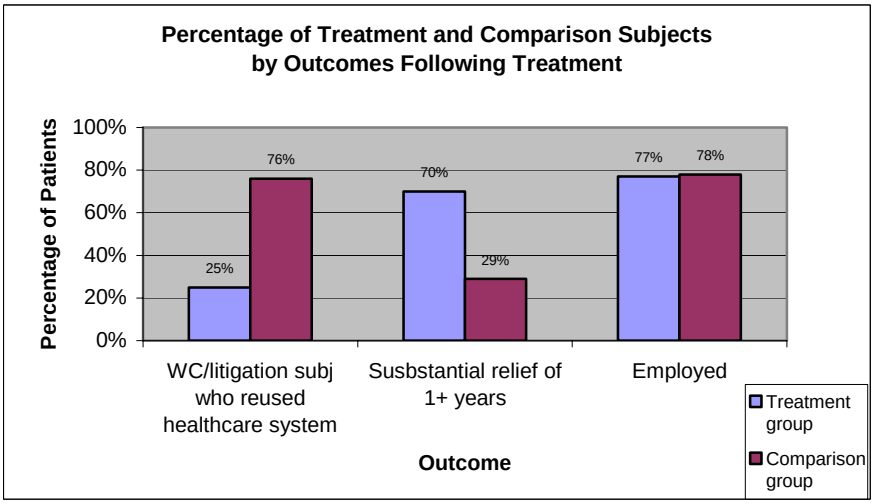
| | Number of Patients | Number (%) Available for Follow-up |
|---|---|---|
| Completed the program | 627 | 495 (79%) |
| Dropped out | 161 | 122 (76%) |
| Comparison group (elected not to participate) | 107 | 83 (78%) |

Results: Follow-up occurred at an average of 13 months.

Static strength, sagittal ROM, and dynamic strength in the sagittal and rotational planes improved significantly.

71% of patients indicated that they had a substantial improvement in their perceived ability to perform the activities of daily living.




Conclusion: Despite methodological limitations, results show that patients who had been told that they needed surgery were able to avoid surgery in the short term by engaging in aggressive strengthening exercise.

## III. RCT with Low Back Pain Subjects

a. Risch examined whether lumbar extension exercise would increase strength and decrease pain in a diverse chronic low-back pain population. The study randomly assigned subjects to either a treatment group (n=31) or a waitlist control group (n=23). The treatment group participated in variable resistance dynamic exercises twice a week for 4 weeks and then once a week for 6 weeks. (Risch 1993)

The weight load equaled one half of the subject's peak isometric strength. Subjects completed as many repetitions as possible until they experienced fatigue. When a subject exceeded 12 repetitions, the torque was increased 5 ft-lbs.

Study Population: The study included 54 ambulatory patients with an average age of 45 years. Subjects experienced low back pain for an average of 8 years. 54% of subjects received workers' compensation or disability payments. Time off of work because of pain averaged 37 months.

Subject Diagnoses

| Diagnosis | Percent of Patients |
|---|---|
| low back pain with sciatica | 56% |
| low back pain without sciatica | 43% |
| myofacial syndrome | 50% |
| spinal stenosis | 28% |
| lumbar spondylosis | 46% |
| lumbar instability | 43% |

Results: At baseline, the groups differed significantly in the time that had elapsed since working. A longer period of time had passed for the control group compared to the treatment group. The control group also reported more physical and psychosocial dysfunction compared to the treatment group at pretreatment.

After controlling for differences, the groups differed significantly on the physical dysfunction scale. However, the researchers did not detect differences between groups for psychological distress or psychological well-being. Finally, the treatment group reported a significant reduction in pain, and the control group reported an increase in pain.

Results also indicated that the treatment group significantly increased their strength at all angles within the patient's ROM.

Factors were entered into a stepwise regression model to assess pretreatment predictors of therapeutic gain. Pain and posttreatment strength gains accounted for 19% of the total variance in the model and significantly influenced strength outcomes.

Conclusion: The findings indicate that exercising the lumbar extensor muscles increased low-back strength in chronic low back pain patients. The increased strength was associated with perceived improvements in physical and psychosocial functioning. However, subjects did not experience changes in self-reported daily activities.

## Costs

In 1996, the MedX Utilization Steering Committee recommended the following fees. (MedX 1995)

| | Type of Patient | | | | | |
|---|---|---|---|---|---|---|
| | Low Back | | Cervical | | Lumbar and Cervical | |
| | 8 weeks | 12 weeks | 8 weeks | 12 weeks | 8 weeks | 12 weeks |
| extension only | $1095-$1335 | $1460-$1940 | $1335 | $1940 | $2430-$2670 | $3400-$3880 |
| extension and rotation | $2190-$2670 | $2920-$3880 | $2670 | $3880 | $2750 | $4000 |

In 1999, Nelson's research involved completing the exercise program in 21 visits over 10 weeks, which cost an average of $1,950. (Nelson 1999) Leggett reported that costs for a typical program consisted of 2 days per week for 8 weeks equaled $1900. (Leggett 1999)

In August 2003, the Department of Labor and Industries accepted the following physical therapy codes.

| CPT Code | Description | Number of Allowed Requests | Average Charge | Average Allowed |
|---|---|---|---|---|
| 95831 | Muscle testing, manual (separate procedure) with report; extremity (excluding hand) or trunk | 18 | $44.01 | $34.35 |
| 95851 | Range of motion measurements and report (separate procedure); each extremity (excluding hand) or each trunk section (spine) | 26 | $54.12 | $35.25 |
| 97001 | Physical therapy evaluation | 1744 | $96.74 | $85.91 |
| 97110 | Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility | 23051 | $72.95 | $60.51 |

## Insurers

Aetna considers the use of MedX lumbar/cervical extension machine for muscle testing experimental and investigational.

The August 2003 policy states that MedX "has not been adequately validated as a test of isometric and isokinetic muscle strength in persons with back or neck pain. In addition, the MedX machine has not been shown to be superior to any other particular brand of exercise equipment when used for administering physical therapy." (Aetna 2003)

In 1994, BlueCross BlueShield (BCBS AL) of Alabama determined that therapy provided with MEDX equipment is considered investigational. (BCBS 1994)

In 2001, the Medicare Part B Carrier for Arizona decided not to cover MEDX treatments. The decision is based on the advice of Physical Therapy consultants. They request practitioners to use procedure code 97799, unlisted physical medicine/ rehabilitation service or procedure, and enter "MEDX" on the narrative page. (BCBS AZ 2001)

## Conclusion

Several studies have been conducted to examine the effectiveness of the MedX Lumbar Extension Machine for strengthening the lumbar extensor muscles and for treating low back pain. The majority of data comes from case series studies that lack comparison groups. Without comparison groups, it is not possible to establish a causal relationship between the MedX exercise program and clinical outcome.

A randomized controlled trial with asymptomatic subjects compared exercise with pelvic stabilization against exercise without pelvic stabilization. The results suggested that both groups improved dynamic trunk extension strength. Another randomized controlled trial with low back pain patients compared MedX to no treatment. The MedX group reported a reduction in pain while the control group reported an increase in pain. Results also indicated that the treatment group increased their strength at all angles within the patient's ROM.

The evidence suggests that MedX may help to increase lumbar muscle strength. However, studies do not clearly show MedX's efficacy over other exercise programs.

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**Appendix A:** Definitions for Classification of Evidence

| Rating of recommendation | Translation of evidence to recommendations | Rating of Therapeutic Article |
|---|---|---|
| (note: technology assessment ratings in parentheses)<br><br>A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population | Level A rating requires at least two consistent Class I studies* | **Class I:** Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required:<br>a) primary outcome(s) is/are clearly defined<br>b) exclusion/inclusion criteria are clearly defined<br>c) adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias<br>d) relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences. |
| B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population | Level B rating requires at least one Class I study or two consistent Class II studies | **Class II:** Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a RCT in a representative population that lacks one criteria a-d. |
| C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population | Level C rating requires at least one Class II study or two consistent class III studies | **Class III:** All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.** |
| U = Data inadequate or conflicting. Given current knowledge, treatment (test, predictor) is unproven | Studies not meeting criteria for class I-class III | **Class IV:** Evidence from uncontrolled studies, case series, case reports, or expert opinion. |

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria met, 2) magnitude of effect ≥5, and 3) narrow confidence intervals (lower limit >2).
***Objective outcome measurement*—an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).